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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|-------------------------------|------------------|
| 10/634,288 | 08/05/2003 | Patrick Michael O'Brien | PC25268A | 8930 |
| 28880 | 7590 | 08/25/2005 | EXAMINER | |
| WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105 | | | BALASUBRAMANIAN, VENKATARAMAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,288

Applicant(s)

O'BRIEN, PATRICK MICHAEL

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-16 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 7 and 9-16 drawn to a compound of formula I, wherein Y¹ is O, namely bicyclooxazinone compound, composition and method of use, classified in class 544, subclasses 105 and others, class 514, subclasses 230.8 and others depending upon the preferred embodiments of other heterocyclic or heteroaryl groups. .
- II. Claims 1-5 and 8-16 drawn to a compound of formula I, wherein Y¹ is S, SO, SO₂ namely bicyclothiazinone compound, and composition and method of use, classified in class 544, subclasses 48, 51 and others, class 514, subclasses 224.2 and others depending upon the preferred embodiments of other heterocyclic or heteroaryl groups. .
- III. Claims 1, 4-6 and 9-16, drawn to a compound of formula I, wherein Y¹ is CH₂, Y⁵, Y⁶ and Y⁸ are nitrogen, namely bicyclotriazine compound, composition and method of use, classified in class 544, subclass 184, class 514, subclasses 243 and others depending upon the preferred embodiments of other heterocyclic or heteroaryl groups. .
- IV. Claims 1, 4-6 and 9-16, drawn to a compound of formula I, wherein Y¹ is CH₂, Y⁵, Y⁶ are nitrogen and Y⁸ is C(R⁵), namely bicyclopriyridazine compound, composition and method of use, classified in class 544,

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subclass 236, class 514, subclass 248 and others depending upon the preferred embodiments of other heterocyclic or heteroaryl groups.

- V. Claims 1, 4-6 and 9-16, drawn to a compound of formula I, wherein Y^1 is CH_2 , Y^6 , Y^8 are nitrogen and Y^5 is $C(R^5)$, namely bicyclopymidine compound, composition and method of use, classified in class 544, subclass 279, class 514, subclass 258 and others depending upon the preferred embodiments of other heterocyclic or heteroaryl groups.
- VI. Claims 1, 4-6 and 9-16, drawn to a compound of formula I, wherein Y^1 is CH_2 , Y^5 , Y^8 are nitrogen and Y^6 is $C(R^5)$, namely bicyclopiazine compound, composition and method of use,, classified in class 544, subclass 350, class 514, subclasses 249 and others depending upon the preferred embodiments of other heterocyclic or heteroaryl groups.
- VII. Claims 1, 4-6 and 9-16, drawn to a compound of formula I, wherein Y^1 is CH_2 , one of Y^5 , Y^8 and Y^6 is nitrogen, the other two $C(R^5)$, or Y^5 , Y^8 are and Y^6 are $C(R^5)$, namely bicyclopiazine compound, composition and method of use, classified in class 546, subclasses 118, 153, class 514, subclasses 300, 312 and others depending upon the preferred embodiments of other heterocyclic or heteroaryl groups..

The inventions are distinct, each from the other because of the following reasons:

As per MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent or distinct as claimed and

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(B) There must be a serious burden on the examiner if restriction is required.

Invention I, II, III, IV, V, VI and VII are independent and distinct from each other because they are directed to structurally dissimilar compounds with distinct Y¹, Y⁵, Y⁶ and Y⁸ choices that lack common core, namely, bicyclothiazinone versus bicyclooxazinone versus bicyclotriazine versus bicyclopyridazine versus bicyclopyrimidine versus bicyclopyrazine versus bicyclopyridinone core compounds. Consequently, the groups have different classifications and require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. For example prior art cited in the Information Disclosure Statement may not be applicable to all the above groups. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

In addition, it is necessary to classify and search all the controlling cores generically embraced in Group I, II, III, IV, V, VI and VII along with various choices of heterocyclic ring embraced variable groups. Such a search of all controlling cores would be a serious search burden.

This application contains claims directed to the following patentably distinct species of the claimed invention with variety of Y¹, Y⁵, Y⁶ and Y⁸ substituents. See claims 10 and 11

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-9 and 12-16 are generic.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In view of distinct nature of each of the invention, the restriction is set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Acting Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is (571) 272-0661.

The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

Venkataraman Balasubramanian
Venkataraman Balasubramanian

8/23/2005